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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,845	01/13/2000	DAVID A. ESTELL	GC382-US	5579

7590 06/28/2002

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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/28/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/462,845	ESTELL, DAVID A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Yong Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 12 April 2002.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-7,9-11 and 16-19 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-7,9-11 and 16-19 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

### **DETAILED ACTION**

The amendment filed on April 12, 2002, canceling claim 21 and amending claims 1-3, 5, 7, 9-11 and 17-18, has been entered. This application is a 371 of PCT/FI99/00410.

Claims 1-7, 9-11 and 16-19 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-11 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. in view of Kunst et al.

Nakamura et al. (form PTO-892) teach a *Bacillus subtilis* strain deficient in *apr*, *npr* and genes encoding serine proteases (page 2367, 3<sup>rd</sup> paragraph). Nakamura et al. teach a vector system comprising said DNA, host cell comprising the vector and a method of producing heterologous enzymes with the said host cell (abstract, page 2367, pages 2368-2369 and 2372). Nakamura et al. also teach that the *Bacillus* organism

produces only small amounts of heterologous proteins due to degradation by extracellular and intracellular proteases (page 2367). Regarding claims 4-7, the *Bacillus* microorganism is capable of expressing the enzymes listed in claim 7.

The difference between the reference of Nakamura et al. and the instant invention is that Nakamura et al. do not teach a microorganisms comprising a mutated or deleted gene encoding a serine protease, wherein said gene comprises SEQ ID NO:1.

Kunst et al. (form PTO-892 – Yuxl Bacsu) teach a DNA molecule encoding a serine protease that is 100% identical to SEQ ID NO:2 of the instant invention (Sequence Search).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make a *Bacillus* comprising a mutated or deleted serine protease gene, apr or npr gene and to use the microorganism in production and secretion heterologous enzymes without proteolytic degradation. The motivation of using such a host system is to decrease proteolytic activity during the production and secretion of the heterologous protein by effectively deleting the genes encoding proteases instead of adding protease inhibitors to a living organism. One of ordinary skill in the art would have had a reasonable expectation of success since recombinant production of heterologous proteins in *Bacillus* is routinely performed in the art.

***Response to Arguments***

Applicant's arguments filed December 6, 2001 have been fully considered but they are not persuasive.

***Claim Objections***

Applicants argue that the numbering of Claims 13-20 were correct. The examiner disagrees. Since there was no Claim 12, claims 13-20 were renumbered as 12-19 under 37 CFR 1.126. Claims must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 17-20 have been renumbered as claims 16-19.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak  
Patent Examiner

June 20, 2002



PONNATHAPU ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
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